

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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TO: Codex Contact Points
Interested International Organizations

FROM: Secretary, Codex Alimentarius Commission
Joint FAO/WHO Food Standards Programme, FAO, 00100 Rome, Italy

SUBJECT: **Proposed Draft Working Principles for Risk Analysis for Food Safety**

DEADLINE: **5 October 2004**

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The 20th Session of the Committee on General Principles considered the *Proposed Draft Working Principles for Risk Analysis for Food Safety* and decided to return them to Step 3 and to request further government comments on the current document CX/GP 04/20/4. These comments, together with the comments already received would be reviewed by a meeting of a Working Group to be held in conjunction with the 21st session of the Committee in November 2004, with a view to preparing a revised version of the *Principles*. The Working Group would be co-chaired by Canada and Argentina and would be open to all governments and observers wishing to participate. The Committee would consider the *Proposed Draft Working Principles* at its 22nd session at Step 4, together with all the comments received, taking into account the outcome of the Working Group (ALINORM 04/27/33A, para. 43).

The Working Group will be held on Saturday 6 November 2004 in the Centre International de Conférence BERCY, 139 rue de Bercy, 75012 Paris, France, prior to the 21st (extraordinary) Session of the Committee on General Principles (8-12 November 2004). The Proposed Draft Working Principles will be considered by the 22nd (regular) Session of the Committee (Paris, France, 11-15 April 2005).

Governments and international organizations wishing to submit comments at Step 3 on the Proposed Draft Working Principles should do so in writing, preferably by email, to the above addresses **before 10 October 2004**.

PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS FOR FOOD SAFETY¹

The 16th Session of the Committee on General Principles (2001) considered the Proposed Draft Working Principles for Risk Analysis and asked the Commission whether they were intended exclusively for application in the framework of Codex, or by Member governments, or by both. The 24th Session of the Commission confirmed the initial mandate of the Committee on General Principles to complete the principles for risk analysis within Codex as a high priority and agreed that the Committee should develop guidance to governments subsequently or in parallel, as appropriate in view of its programme of work. The Commission also decided how it should proceed when scientific data were insufficient or incomplete (ALINORM 01/41, paras. 81-83).

The *Proposed Draft Principles Risk Analysis for Application in the Framework of the Codex Alimentarius* were considered and finalized by the following sessions of the CCGP and adopted by the 26th Session of the Commission in 2003, for inclusion in the Procedural Manual.

The 17th Session of the Committee on General Principles agreed to initiate the elaboration of working principles intended for application by governments and this was approved as new work by the 50th Session of the Executive Committee (ALINORM 03/3A, para. 64, Appendix III).

The 18th session considered a first draft of the Proposed Draft Principles for Risk Analysis for Food Safety prepared by the Codex Secretariat. The Committee had a general discussion on the approach to the development of the Principles and the issues that should be addressed but did not reach a consensus on how to proceed further. The Committee requested the Secretariat to redraft the present document on the basis of the following considerations:

- The points raised during the debate, including the written comments submitted;
- Additional comments to be submitted by governments and interested international organizations within a reasonable timeframe;
- An analysis of existing work developed by Codex Committees and Task Forces that provided advice to governments on specific risk analysis issues, with a view to avoiding duplication of work and to identifying gaps; and
- An analysis of related work undertaken by FAO and WHO, including on the practical application of risk analysis.

No additional written comments were submitted after the 18th Session of the Committee.

The Secretariat has therefore redrafted the Proposed Draft Principles, taking into account the discussions held at the 18th Session of the Committee and the comments submitted in CX/GP 03/4. The introductory part of the document also discusses the possible approaches to further work in view of the discussion and comments made, as the Committee will need to decide how to proceed before considering a specific document.

As regards existing work developed by Committees and Task Forces, there has been no change since the 18th Session. As indicated in the earlier version of the document and in the discussion in Annex 1, recommendations to governments have been developed by the Committee on Food Hygiene and by the *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology. The other committees that are currently considering risk analysis guidance are proposing recommendations intended for application within the framework of Codex, not by governments. This is the case of the Committee on Food Additives and Contaminants, the Committee on Residues of Veterinary Drugs in Foods and the Committee on Pesticide Residues.

The introductory part of the document indicates how the recommendations of the FAO/WHO Expert Consultations have been incorporated into the Proposed Draft Principles. The questions to be addressed by the Committee, and the amendments made to the earlier version are discussed in the introductory part of the document as Annex 1, while the revised text of the Proposed Draft Principles is presented in Annex 2.

¹ Circulated for the 20th session of the CCGP as CX/GP 04/20/4

INTRODUCTION

A. General Approach

The views expressed in the written comments and in the discussion during the 18th Session of the Committee did not allow to reach a consensus on the approach to the development of the principles of risk analysis intended for governments. The Committee will therefore need to consider whether it should proceed with the development of principles for risk analysis intended for governments to be developed as a Codex document.

Some delegations questioned the need for this document due to the following reasons: Codex Committees had already developed (or were in the process of developing) risk analysis guidance that applies to member countries in specific areas; and the guidance provided in the document may not be of benefit to Members in view of their rights and obligations under the WTO agreements (ALINORM 03/33A, paras. 33-34).

The current Codex texts on risk analysis applying to specific areas are the following:

Food Hygiene

- *Principles and Guidelines for the Conduct of Microbiological Risk Assessment*(CAC/GL 30-1999)

Foods Derived from Biotechnology

- *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* (CAC/GL 44-2003)
- *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003)
- *Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms*(CAC/GL 46-2003)

Since the last session of the Committee, the texts regarding biotechnology were adopted by the 26th Session of the Commission as final texts but no other developments have occurred in this area. In the Committee on Food Hygiene the *Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management* have been discussed for several years and are still under consideration at Step 3. This is the only document on risk analysis intended for governments and for Codex currently under consideration in the framework of Codex.

As regards the discussion concerning the application of the WTO Agreements and in particular the SPS Agreement, the main issue relates to the section on precaution on risk management. Some comments proposed to eliminate this section (paragraph 32) as it interferes with the establishment of interim measures that is addressed under Article 5.7 of the SPS Agreement. The Committee will need to discuss whether the section should be deleted or retained, taking into account the amendments proposed by several countries in their comments.

If it is not possible to reach consensus on some aspects of risk management, or on the risk management section as a whole, the Committee may also postpone consideration of risk management and concentrate on the other aspects of risk analysis where it might be possible to reach consensus, as a first stage.

Some comments question the format and type of guidance proposed to government on risk analysis, and propose to provide more practical guidance to governments on how to proceed on risk analysis. However, when the elaboration of a new document directed to governments was proposed by the 17th Session of the Committee and approved as new work, it was agreed to develop principles, with the understanding that the format was similar to that of the *Working Principles* for Codex application, the only difference being the scope. It was not proposed to develop guidelines or a manual for practical application in the framework of Codex as this is rather the competence of FAO and WHO .

As regards the practical application of risk analysis, FAO and WHO are developing a Manual on risk analysis : “Food Safety Risk Analysis - An Overview and Framework Manual” that is in the process of finalization. The manual has been developed to improve food safety regulators’ understanding and use of risk analysis as the basic framework for a modern food safety system. It is intended to provide essential background information and guidance for regulators and other officials responsible for managing and/or supervising risk analysis in practice. It presents a framework and principles to structure and guide the

application of risk analysis rather than a prescriptive formula to implement risk analysis. This manual will be the first part of a three-part set, which encompasses:

Part I: Food Safety Risk Analysis – An Overview and Framework Manual

Part II: Food Safety Risk Analysis Case Studies

Part III: Resources for Building Capacity in Food Safety Risk Analysis (CD-ROM)

Further update on the development of the Manual will be presented by FAO and WHO during the 20th Session of the Committee.

Another issue to be addressed is whether the principles intended for governments are or should be essentially different from those applied in the framework of Codex. The *Working Principles* applicable within Codex and adopted in 2003 were largely based on the recommendations of the FAO/WHO Expert Consultations that addressed the general aspects of risk analysis:

- Application of Risk Analysis to Food Standards Issues (1995)
- Risk Management and Food Safety (1997)
- The application of Risk Communication to food Standards and Safety Matters (1998)

The purpose of the consultations was to advise FAO, WHO and member governments about risk analysis. They addressed risk analysis as a whole on the basis of current work in different areas of food safety, and included recommendations addressed to Codex, to FAO/WHO and to governments. These recommendations were incorporated into the *Working Principles* that were subsequently adopted and reflect consensus on the principles of risk analysis.

The Committee may wish to discuss whether the guidance provided by these consultations is still applicable to define the basic principles of risk analysis when applied to governments. If this is not the case, it might be necessary to ask for additional guidance from FAO and WHO on risk analysis with a specific focus on governments.

As regards the relation with other Codex texts addressing risk analysis, the adopted *Working Principles* had taken into account the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* in the development of the risk assessment section, most of which is also used in the Proposed Draft Principles intended for governments. It may be noted that the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* are of general application and do not specify in the Scope that they are intended for use in a specific framework (such as Codex or governments).

The first version of the Proposed Draft Working Principles for Risk Analysis intended for governments took into account the specific work in the area of foods derived from biotechnology, especially as regards post-market monitoring and product tracing, that were specifically addressed in the *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*.

Some comments also pointed out that the Proposed Draft Principles intended for governments duplicated the text of the adopted *Working Principles* in several sections. In order to avoid repetition, an option would be to mention the relevant sections of the adopted *Working Principles* only by reference and to add only the provisions that are specifically intended for governments.

Summary of possible options

The Committee may therefore wish to consider the following questions:

- whether work should proceed on the development of risk analysis principles intended for governments;
- whether the format of the document as basic principles should be retained;
- whether the principles applicable within Codex can be used as a basis for discussion with the required changes to make them applicable to governments, or if another approach is preferable such as:
 - referring only to the recommendations of FAO/WHO Expert Consultations
 - additional guidance from FAO/WHO concerning general risk analysis principles for governments

If principles intended for governments are to be developed, the Committee may consider including only a reference to the sections that are already included in the adopted *Working Principles*, and retaining the sections that are specifically intended to governments.

As it may be difficult to reach consensus on some aspects of risk management, the Committee may consider

- whether this document should include the section on risk management or separate it in a first stage in order to concentrate on the areas where consensus appears more likely and to advance them to further steps
- if the section on risk management is retained, whether it should include the section on precaution in risk management, with the understanding that a general reference to precaution in risk analysis is retained in paragraph 9
- replacing the section on risk management with a reference to the recommendations of the FAO/WHO Expert Consultation on Risk Management and Food Safety

However, it appeared from the written comments that several countries agreed to proceed with consideration of the document in its present format and proposed specific amendments. Should the Committee decide to proceed with the consideration of the document, the text attached as Annex 2 may be used as a basis for discussion. The text was redrafted in the light of the comments submitted on the earlier version in CX/GP 04/3, as follows.

B. Proposed Draft Working Principles for Risk Analysis – Redrafted version

Title

As the document is intended for governments, it is proposed to refer to “principles” as this would simplify the title and ensure consistency with the other texts addressing risk analysis and/or risk assessment intended for governments. The use of the term “working principles” was more relevant in the framework of Codex as the principles were intended for direct or practical application for Codex purposes. In view of some comments that questioned the reference to “food safety” or proposed alternative wording, it is proposed to go back to the initial title referring only to risk analysis. The adopted *Working Principles* for use in the framework of Codex do not refer to “risk analysis for food safety” as this is clear enough in view of the context and of the mandate of the Codex Alimentarius Commission. In the present document this is also explained in the Scope and it is therefore proposed to simplify the title to “**Proposed Draft Principles for Risk Analysis**”.

As indicated in the earlier version, the footnote is for clarification purposes and should be deleted when the Principles are adopted and incorporated into the Codex Alimentarius.

Scope

The scope was amended in order to simplify the wording in view of the comments received. Although some comments proposed alternative text, the reference to “food safety” was retained since it is defined in the framework of Codex (*General Principles of Food Hygiene*) and should not create any confusion.

Risk Analysis – General Aspects

The amendments made to the section are mainly for clarification and simplification purposes in the light of the comments received. In paragraph 7, the text was amended in order to reflect more realistically the application of risk analysis at the national level, as proposed in the comments.

As regards the consistency of the process, on which some clarification was required in the comments, the *FAO/WHO Expert Consultation on Risk Management and Food Safety* indicate that member countries “are required to ensure that risk management decisions are transparent, and not arbitrary or unjustifiably different (i.e. are consistent).” (Section 4. International Trade), so consistency should be ensured between decisions or measures taken in the framework of risk management.

Risk Assessment

The relevance of the first paragraph in the section on risk assessment or the section on risk management had been discussed earlier and was raised in the written comments. As this is a general principle (adapted from the *Statements of Principles Relating to the Role of Food Safety Risk Assessment*), it is proposed to transfer it to the general section on risk analysis as it affects the entire process, with an editorial change proposed in the comments.

Paragraph 16 was amended as proposed in the comments to address the case where risk assessment is carried out by government experts, and the current text concerning other experts was retained.

The reference to relevant “ecological and environmental conditions” was added in paragraph 18 and in the corresponding paragraph in the Risk Management section, as proposed in the comments to reflect the importance of these conditions on the development of pathogens such as biotoxins. A reference to “transport” practices was also added as this is part of the food chain.

Paragraph 19 was slightly amended for clarification purposes and placed after paragraph 20 in order to improve the logical order of the section.

In paragraph 21, the provisions on the report of the risk assessment were completed to provide all relevant information, improve the transparency of the process, as proposed in the comments, since the current text referred only to the constraints and uncertainties. As regards the responsibilities for resolving the impact of uncertainty on risk management decisions, it was noted that the section on risk management should provide guidance to risk managers in this respect and the Committee will need to consider this issue.

Risk Management

The elements of the structured approach are described as in the *FAO/WHO Expert Consultation on Risk Management and Food Safety*. The Joint *FAO/WHO Consultation on Principles and Guidelines for Incorporating Microbiological Risk Assessment in the Development of Food Safety Standards* agreed to replace the term “risk evaluation” by “preliminary risk management activities” and to refer to the “evaluation” of risk management options, and the text was amended accordingly. This is also consistent with paragraph 28 of the adopted *Working Principles*.

Paragraph 24 was initially based on Principle 2 of the *FAO/WHO Expert Consultation on Risk Management and Food Safety* that referred to “other factors”. The comments proposed some amendments that were included for further consideration.

A new paragraph 25bis) was introduced concerning the need to document how risk management decisions are identified into national regulations and to facilitate the understanding of risk management. This reflects a similar section in the adopted *Working Principles* (paragraph 31). This paragraph is numbered 25bis) in order to retain the current numbering and to facilitate reference to the earlier document.

The option of not taking any action was introduced in paragraph 26 as proposed in the comments and as this reflected the consensus reached in the discussion of the adopted *Working Principles*.

Provisions for traceability/product tracing had been added to the initial Proposed Draft in view of the decision of the Executive Committee that the first consideration should be given to the use of traceability as a risk management option in the *Working Principles for Risk Analysis* (ALINORM 03/3, para. 31) and on the basis of the text included in the *Principles for Risk Analysis of Foods Derived from Modern Biotechnology*. Paragraphs 28 to 30 on post market monitoring and product tracing were retained with some limited changes, as there seems to be no objection to their inclusion and the Committee will need to consider whether this section should be expanded or amended as proposed in some comments.

Although some specific amendments were proposed to paragraph 32 (precaution in risk management), no specific changes were made as there is no consensus on the inclusion of this paragraph, and the Committee will need to decide first whether it should be retained. The footnote was deleted as in any case, it is left to member countries to refer to provisional measures according to their national regulations and it does not need to be specified in a Codex document.

Several comments point out that the general considerations listed in paragraph 33 should not be limited to interim measures and the introductory text was amended accordingly, as a basis for discussion. Some comments also proposed to transfer some provisions to other sections where they may be more relevant. However, the Secretariat did not amend the rest of the text at this stage as the Committee will need to decide whether these provisions can be discussed separately from paragraph 32.

Risk Communication

Only some editorial changes for clarification purposes were made to the section on Risk Communication as there were few comments on the section.